UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

LAUREN THOMPSON,

Plaintiff

v.

REGENCE BLUESHIELD; EXPEDIA HEALTH & WELFARE BENEFIT PLAN; EXPEDIA, INC., in its capacity as Plan Administrator and/or Plan Sponsor; and MCMC SERVICES, LLC,

Defendants.

No. 2:24-cv-1336

DECLARATION OF SHAILENDER BHATIA, M.D., PROVIDED IN SUPPORT OF PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER

LAW OFFICE OF MEL CRAWFORD
3244 N.E. 103rd St
Seattle, Washington 98125
Tel 206-694-1614 Fax 206-905-2342

Declaration of Shailender Bhatia, M.D.

I, Shailender Bhatia, M.D., depose and declare as follows:

1. I am a physician, licensed to practice in Washington since 2004. I am a medical oncologist specializing in the care of patients with advanced skin cancers, including metastatic melanoma, which generally require systemic surveillance and therapy. I am Board Certified in Medical Oncology, Hematology and Internal Medicine. I serve as the Director of the Melanoma and Renal Cancer Team at the Fred Hutch Cancer Center. I am a Professor in the Clinical Research Division at the Fred Hutch Cancer Center, and a Professor in the Division of Hematology and Oncology at the University of Washington School of Medicine.

2. My research interests include novel therapies that stimulate the immune system to fight cancer and targeted therapies that spare patients unnecessary side effects. I am committed to developing clinical trials that focus on improving outcomes for patients with skin cancers, especially melanoma. A copy of my curriculum vitae is attached at TAB 1.

3. My colleagues and I at the Fred Hutch Cancer Center provide medical care to Lauren C. Thompson, DOB [redacted]. Ms. Thompson, a 39-year-old mother of two young children, has life-threatening, stage IV metastatic melanoma. She has rapidly progressing disease despite prior treatment with ipilimumab, nivolumab, binimetinib, and tumor-infiltrating lymphocytes under a clinical trial. Her melanoma is unresectable, and without effective systemic therapy this young patient's life is at serious risk.

4. It is my professional judgment, and that of our multi-disciplinary oncology team at the Fred Hutch Cancer Center – a team that includes thought leaders in melanoma – that nivolumab-relatlimab-rmbw (Opdualag) is a highly appropriate FDA-approved therapy for Ms. Thompson's refractory and life-threatening melanoma. We have prescribed this treatment, but unfortunately the insurer has repeatedly denied pre-authorization. Copies of our two prior appeals are attached at TABS 2 and 3.

5. It is our prudent clinical judgment that providing this medication to Ms. Thompson is squarely in accordance with generally accepted standards of medical practice. We have several patients in our clinic who received this combination for their refractory melanoma (not front-line setting) and experienced complete remission (i.e. no visible tumors left behind), which has been life saving for these patients. In addition to our own clinical experiences, there are several credible scientific studies published in medical journals that meet nationally recognized requirements for scientific manuscripts, and which submit most of their published articles for review by experts who are not part of the editorial staff, that show strong data regarding the efficacy of nivolumab-relatlimab-rmbw in both front-line *and in refractory melanoma patients*. See Ascierto PA, et al., Nivolumab and Relatlimab in Patients With Advanced Melanoma That Had Progressed on Anti-

Programmed Death-1/Programmed Death Ligand 1 Therapy: Results From the Phase I/IIa RELATIVITY-020 Trial. J Clin Oncol. 2023 May 20;41(15):2724-2735. doi: 10.1200/JCO.22.02072. Epub 2023 Feb 13. PMID: 36780608; PMCID: PMC10431305 (copy attached at TAB 4), reporting on a clinical study that concluded, "Nivolumab and relatlimab had a manageable safety profile and ***demonstrated durable clinical activity in a proportion of patients with heavily pretreated advanced melanoma*** with prior progression on anti-PD-(L)1-containing regimens." See also Xu J, Mu S, Wang Y, Yu S, Wang Z. Recent advances in immunotherapy and its combination therapies for advanced melanoma: a review. Front Oncol. 2024 Jul 16;14:1400193. doi: 10.3389/fonc.2024.1400193. PMID: 39081713; PMCID: PMC11286497 (copy attached at TAB 5), stating that for "advanced melanoma patients who have progressed *after receiving previous treatment* (including anti-PD-1 therapy), relatlimab combined with nivolumab can also bring long-lasting survival benefits." See also Sorino C, Iezzi S, Ciuffreda L, Falcone I. Immunotherapy in melanoma: advances, pitfalls, and future perspectives. Front Mol Biosci. 2024 Jun 28;11:1403021. doi: 10.3389/fmolb.2024.1403021. PMID: 39086722; PMCID: PMC11289331 (copy attached at TAB 6) noting that "the combination of relatlimab and nivolumab had satisfactory and durable clinical results in patients with metastatic melanoma *that were previously treated with PDL-1 inhibitors*."

6. Our determination that nivolumab-relatlimab-rmbw is medically necessary to treat Ms. Thompson's metastatic melanoma is not only in accordance with generally accepted standards of medical practice, and based on credible scientific studies published in nationally recognized medical journals, but also supported by the United States Food and Drug Administration ("the FDA"), which has approved nivolumab-relatlimab-rmbw for treatment of stage IV melanoma, *regardless of the line of therapy*. See the FDA label at TAB 7.

7. Further, use of nivolumab-relatlimab-rmbw for metastatic melanoma is supported by national guidelines, including the National Comprehensive Cancer Network. See the NCCN Guidelines Version 2.2024, for Melanoma: Cutaneous, identifying the medication as a "*preferred regimen*" for "*second-line or subsequent therapy*" for metastatic or unresectable melanoma, at TAB 8, page 211 to this Declaration.

8. Treatment with nivolumab-relatlimab-rmbw is unquestionably clinically appropriate given the type, extent, site and duration of Ms. Thompson's disease and considered effective for her disease.

9. We have not recommended nivolumab-relatlimab-rmbw for our convenience, or the convenience of the patient or any other health care provider.

10. There is *no FDA-approved alternative service or sequence of services that is as likely to produce equivalent therapeutic results* or to be as effective in the treatment of Ms. Thompson's refractory melanoma.

11. The insurer explained its denial with reference to its "Coverage criteria" for nivolumab-relatlimab-rmbw, which it identified as follows:

    - there is a diagnosis of melanoma, unresectable or metastatic.
    - no prior systemic therapy in the advanced disease setting.
    - nivolumab-relatlimab-rmbw (Opdualag) will be used as monotherapy.

    The insurer then stated, "we recognize your patient has metastatic melanoma. However, based on the information provided we are unable to establish that: - your patient has had no prior systemic treatment in the advance setting."

12. This second criterion – that the patient had no prior systemic therapy – is imported from the RELATIVITY-047 clinical trial of nivolumab-relatlimab-rmbw, where the criteria to participate in that trial included that patients "must not have had prior systemic anticancer therapy for unresectable or metastatic melanoma." See TAB 9, Tawbi HA, et al., RELATIVITY-047 Investigators, Relatlimab and Nivolumab versus Nivolumab in Untreated Advanced Melanoma. N Engl J Med. 2022 Jan 6;386(1):24-34. doi: 10.1056/NEJMoa2109970. PMID: 34986285; PMCID: PMC9844513, and TAB 10, the appendix to that article detailing the inclusion criteria. This particular criterion was rational *in the context of clinical trials*, in order to ensure a relatively homogenous cohort of patients. Clinical studies of medications often include such criterion; otherwise it would be difficult to determine the efficacy of the medication being tested. But there is no rational basis to apply that criterion in the context of *standard treatment*. When there are multiple FDA-approved treatment options available for a patient, one regimen will have to be chosen as the first-line option, and others will have to be used sequentially, as needed based on the response to prior regimen(s). In the case of Ms. Thompson, we chose ipilimumab plus nivolumab, also a standard treatment option regardless of the line of therapy, as the first treatment option for her metastatic disease. Denial of this FDA-approved medication, especially given its proven effectiveness in metastatic melanoma, is a completely arbitrary and irrational decision by the insurer with potential grave implications for Ms. Thompson's life.

13. In summary, nivolumab-relatlimab-rmbw is medically necessary to try to control Ms. Thompson's life-threatening cancer. Its use in patients with systemic therapy is well-supported by scientific evidence, is FDA approved and in accordance with national guidelines. Denying this treatment will have grave life-threatening consequences to this young patient's health. There is already a major delay in her care due to the insurer's repeated negligence of their responsibility, despite repeated pleas by our medical team.

I declare under penalty of perjury that the foregoing is true and correct.

Signed at Seattle, Washington this 19th day of August 2024.

Shailender Bhatia, M.D.